K121873

DEC 1 1 2013

AVINENT
Implant System

510(k) Premarket Notification

Section 5 – 510(k) Summary

DATE OF SUBMISSION: 2013-07-08
SUBMITTER NAME: AVINENT Implant System, S.L.
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DEVICE TRADE NAME: AVINENT Implant System
COMMON NAME: Root-form Endosseous Dental Implant
CLASSIFICATION NAME: Root-form Endosseous Dental Implant (21 CFR 872.3640)

PREDICATE DEVICE(S): Biohorizons (K073268)
NobelActive 3.0 (K102436)
Nobel Biocare Endosseous Implants (K041661)
NobelSpeedy (K050406)

DEVICE DESCRIPTION:
The proposed devices are threaded, root-form endosseous implants of various diameters and lengths and corresponding abutments. The following is a list of the diameter / length combinations of the implant body, dental abutment type and maximum available angulation for each specific type of abutment.

Product Family	Connection	Implant Platform	Implant diameter	Implant length
Dental Implant-Coral Line	External Hexagon	3.5	3.3	10,11.5,13
		4.1	3.3	10,11.5,13,15
			3.8	7,8.5,10,11.5,13,15
			4.0	7,8.5,10,11.5,13,15
			4.2	7,8.5,10,11.5,13,15
			4.8	7,8.5,10,11.5,13
		5.1	4.8	7,8.5,10,11.5,13
	Internal Hexagon	3.5	3.3	10,11.5,13,15
		4.1	3.3	10,11.5,13,15

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			3.8	7,8.5,10,11.5,13,15
			4.0	7,8.5,10,11.5,13,15
			4.2	7,8.5,10,11.5,13,15
			4.8	7,8.5,10,11.5,13
Dental Implant-Ocean Line	External Hexagon	3.5	3.5	10,11.5,13,15
			4.0	7,8.5,10,11.5,13,15
		4.1	4.5	7,8.5,10,11.5,13,15
			5.0	7,8.5,10,11.5,13
	Internal Hexagon	3.5	3.5	10,11.5,13,15
			4.0	7,8.5,10,11.5,13,15
		4.1	4.5	7,8.5,10,11.5,13,15
			5.0	7,8.5,10,11.5,13

Abutment Type	Maximum Abutment Angulation
Healing abutment	0 degrees
Cemented-Straight abutment	0 degrees
Cemented-Angled abutment	17 degrees
Temporary abutment	0 degrees
Gold cylinder abutment	0 degrees
Transepithelial abutment	0 degrees
Transepithelial angled abutment	30 degrees

Implants are titanium alloy 6Al 4V, feature internal and external hex implant to abutment connection options and are available with modified surfaces (TiO_2 layer) to promote improved osseointegration.

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Implant abutments are also titanium alloy 6Al 4V. Initial primary stability of the implant when placed in the bone and implant osseointegration are essential to ensure implant success. Furthermore, the mechanical resistance of the implant-abutment connection is essential to ensure correct long-term functional performance of the dental restoration.Instruments and accessories necessary to place implants and abutments also form part of the system. These concepts are the basis upon which the implant system design characteristics and functional performance are established.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, the AVINENT implant system is compared with the following previously cleared devices:

- Biohorizons (K073268)
- NobelActive 3.0(K102436)
- Nobel Biocare Endosseous Implants (K041661)
- NobelSpeedy (K050406)

Comparison of the proposed devices with the predicate devices is summarized in the following table:

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SUMMARY OF COMPARISON WITH PREDICATE DEVICE:	EXTERNAL CONNECTION			INTERNAL CONNECTION		
	Proposed Device	Predicate Device		Proposed Device	Predicate Devices	
	AVINENT Implant SystemC.Ext.	K041681 Nobel BiocareEndosseous Implants	K050406 Nobel Speedy	AVINENT Implant SystemC.Int.	K073268Biohorizons	K102436 Nobel Active 3.0
Material	Titanium Grade 5 (TiAl6V4 ELI)	Titanium CP Grade 4	Titanium CP Grade 4	Titanium Grade 5 (TiAl6V4 ELI)	Titanium Grade 5 (TiAl6V4 ELI)	Titanium CP Grade 4
Form / Features	Root-form, tapered, microthread, self-tapping with hexagonal external connection.	Straight or tapered implant. External connection system.	Tapered implant with a pronounced apical taper. External connection system.	Root-form, microthread, self-tapping with hexagonal internal connection.	Antomically tapered dental implant body. Aggressive buttress threads. Internal connection system.	Small diameter (3.0mm) internal connection system.
Diameter Ø prosthetic connection:	3.5 to 5.1 mm	3.5 to 6.0 mm	3.5 to 6.0 mm	3.5 to 5.1 mm	3.5 to 6.0 mm	3.0 mm
Diameter Ø endosseous:	3.3 to 5.0 mm	3.3 to 6.0 mm	3.3 to 6.0 mm	3.3 to 5.0 mm	3.5 to 6.0 mm	3.0 mm
Range of lengths	7.0 to 15.0 mm	7.0 to 18.0 mm	7.0 to 18.0 mm	7.0 to 15.0 mm	9mm, 10.5 mm, 12 mm, 15 mm.	10.0 to 15 mm
Surface Treatment to promote implant fixation.	BAS – Biomimetic Advanced Surface: shot-blasted and anodized to form titanium oxide layer on implant threads and collar.	TiUnite® titanium oxide layer from implant threads onto implant collar.	TiUnite® titanium oxide layer from implant threads onto implant collar.	BAS – Biomimetic Advanced Surface: shot-blasted and anodized to form titanium oxide layer on implant threads and collar.	RBT - roughened (shot-blasted) or coated (hydroxylapatite) threaded surface, micro-machined grooves on implant collar.	TiUnite® titanium oxide layer from implant threads onto implant collar.
Abutment Material	Titanium Grade 5 (TiAl6V4 ELI) and PEEK	-	-	Titanium Grade 5 (TiAl6V4 ELI) and PEEK	Titanium Grade 5 (TiAl6V4 ELI) and PEEK	Titanium Grade 5 (TiAl6V4 ELI)
Implant / Abutment Connection	External Hex	External Hex	External Hex	Internal Hex	Internal Hex	Internal Morse Taper
Abutment forms / features	Straight and angled up to 30°	Straight and angled up to 30°	-	Straight and angled up to 30°	Straight and angled up to 25°	Straight and angled up to 15°

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INTENDED USE:
As established in the Indications for Use Statement:

The AVINENT dental implant system is for oral endosseous implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients.
AVINENT implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations.
Implants are intended for immediate loading on single-tooth and/or multiple tooth applicationswhen good primary stability is achieved and with appropriate occlusal loading, to restore chewing function if the requirements detailed in the surgical manual are satisfied.
Specific indications for small diameter (Ø3.3 mm implants):
Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in maxillary lateral incisors or mandibular central and lateral incisors.

The implant system serves as anchorage for dental prosthetic restorations. Implants are placed in the bone of the upper or lower jaw. Abutments are placed into the dental implant to provide support for the prosthetic reconstruction including abutments for cemented restorations to achieve better esthetics. Abutments can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a dental implant system and following all indications set out in FDA Document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Bench testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including mechanical performance (fatigue) testing, biological testing taking account of the level and duration of contact with the body, surface finish testing, packaging validation and sterilization process validation.

SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device.

CONCLUSIONS:
We believe the intended use, the indications for use and performance of the AVINENT implant system is the same as the intended use, indications for use and performance of the predicate devices. We also believe that the AVINENT implant system does not suppose any new or increased risk compared with the predicate devices. Based on the information included in this submission, we conclude that the AVINENT implant system is substantially equivalent to the listed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2013

Avinent Implant System, S.L.
Ms. Anna Cortina
Regulatory Affairs/R&D Manager
POL. IND. Santa Anna, APARTAT 20
Santpedor, Barcelona 08251
SPAIN

Re: K121873
Trade/Device Name: Avinent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 27, 2013
Received: December 2, 2013

Dear Ms. Cortina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer-S for

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 – Indications for Use Statement

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: K121873

Device Name: AVINENT IMPLANT SYSTEM

Indications for Use:

The AVINENT dental implant system is for oral endosseous implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients.
AVINENT implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. Implants are intended for immediate loading on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function if the requirements detailed in the surgical manual are satisfied.

Specific indications for small diameter (Ø3.3 mm implants):

Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in maxillary incisors or mandibular central and lateral incisors.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

Mary S. Runner -S
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